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FED - J0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

CFR

Type Memo Tag

Regulation Definition

Interpretive Guideline

FED - J0003 - COMPLIANCE WITH FED,STATE,& LOCAL LAWS

Title COMPLIANCE WITH FED,STATE,& LOCAL
LAWS
CFR 491.4

Type Condition

Regulation Definition

The rural health clinic and its staff are in compliance with applicable Federal, State, and local laws and regulations.

Interpretive Guideline

The RHC and its staff are in compliance with applicable Federal, State, and local laws and regulations.

A. Federal Laws and Regulations.--The Federal regulations governing the certification of RHCs were published in the Federal Register on July 14, 1978, 43 FR 136. Conditions for certification under those regulations are the subject of these guidelines.

B. State Laws and Regulations.--All States have practice acts that govern the activities of health professionals. While there is considerable variation in the States' practice acts concerning physician assistants, nurse practitioners and certified nurse-midwives, there is a broad mandate in the medical practice acts of all States giving physicians authority to diagnose and treat medical conditions. The extent to which the physician may delegate these responsibilities and to whom, and under what conditions, varies in the States. Some States have updated their practice acts since the advent of the physician assistant, nurse practitioner and certified nurse-midwife health care professionals. In some instances, these updated practice acts have included definitions and specific references to permitted/prohibited activities, supervision/guidance required by a physician, and location/situations in which nurse practitioners, certified nurse-midwives and physician assistants may function. In some States where nurse practice acts have not been significantly updated, some functions of the nurse practitioner are viewed as an extension of the traditional nursing role as being covered by the existing nurse practice act.

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Rural health clinics can be certified only if the State permits--that is, does not explicitly prohibit--the delivery of primary health care by a nurse practitioner, certified nurse-midwife or a physician assistant. The surveyor will encounter wide variations in the wording, interpretation, and application of States' practice acts as they affect the physician assistant, nurse practitioner and certified nurse-midwife in the RHC setting.

In situations where the State law is silent, or where the State law does not specifically prohibit the functioning of a physician assistant, nurse practitioner or certified nurse-midwife with medical direction by a physician and with the degree of supervision, guidance, and consultation required by the RHC regulations, the surveyor may consider this condition as being met. Interpretations needed on specific aspects of the State's practice act should be sought through the State regulatory agency or board(s) dealing with the practice and profession.

FED - J0004 - LICENSURE OF CLINIC

Title LICENSURE OF CLINIC

CFR 491.4(a)

Type Standard

Regulation Definition

The clinic or center is licensed pursuant to applicable State and local law.

Interpretive Guideline

FED - J0005 - LICENSURE/CERT/REGISTRATION OF PERSONNEL

Title LICENSURE/CERT/REGISTRATION OF

PERSONNEL
CFR 491.4(b)

Type Standard

Regulation Definition

Staff of the clinic are licensed, certified or registered in accordance with applicable State and local laws.

Interpretive Guideline

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FED - J0006 - LOCATION OF CLINIC

Title LOCATION OF CLINIC

CFR 491.5

Type Condition

Regulation Definition

Location of Clinic

Interpretive Guideline

Consult with the RO to preliminarily ascertain that a clinic meets the basic requirement of location prior to scheduling a survey. The clinic must be located in a rural area that is designated as a shortage area. Applicants determined not qualified under this requirement should be sent a letter (see Exhibit 27) with the appropriate notation.

A. Rural Area Location.--The law requires the clinic to be located in an area "that is not an urbanized area as defined by the Bureau of the Census." The Bureau has published both a narrative definition of an urbanized area and maps displaying the land area of urbanized areas. Lists and maps of the urbanized areas are contained in the "number of inhabitants" census volume for that State (census of population series PC-80-1-A). Note that this definition is different from that of a metropolitan statistical area (MSA). Contact the Bureau of the Census ROs or the CMS ROs for a determination on whether the clinic is located in a nonurbanized area.

B. Shortage Area Designation.--After it has been ascertained that the clinic is located in a nonurbanized area, the CMS RO will certify whether or not the clinic is located in a designated shortage area. The CMS RO, after consulting with PHS RO staff, promptly responds in writing to the request for a determination. This information may be given by telephone as long as it is followed by a written response. This consultation explores designation:

- o As an area with a shortage of personal health services under §330(b)(3) or 1302(7) of the PHS Act;
- o As a health manpower shortage area described in §332(a)(1)(A) of the PHS Act;
- o As an area which includes a population group which the Secretary determines has a health manpower shortage under §332(a)(1)(B) of the PHS Act;
- o As a high migrant impact area described in §329(a)(5) of the PHS Act; or
- o As an area designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

These designatlb»□

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FED - J0007 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.5(a)

Type Standard

Regulation Definition

The clinic is located in a rural area that is designated as a shortage area, and may be a permanent or a mobile unit.

Interpretive Guideline

FED - J0008 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.5(a)(3)(i)

Type Element

Regulation Definition

The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

Interpretive Guideline

FED - J0009 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.5(a)(3)(ii)

Type Element

Regulation Definition

The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic are housed in a mobile structure, which has fixed, scheduled

Interpretive Guideline

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location(s).

FED - J0010 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

CFR 491.5(b)

Type Standard

Regulation Definition

Interpretive Guideline

The facility must meet location eligibility in a rural health shortage area by one of two provisions, either 491.5(b)(1) or 491.5(b)(2).

FED - J0011 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

CFR 491.5(b)(1)

Type Element

Regulation Definition

Interpretive Guideline

A facility certified under this subpart will not be disqualified if the area in which it is located subsequently fails to meet the definition of rural shortage area.

FED - J0012 - LOCATION ELIGIBILITY EXCEPTIONS

Title LOCATION ELIGIBILITY EXCEPTIONS

CFR 491.5(b)(2)

Type Element

Regulation Definition

Interpretive Guideline

A private nonprofit facility may be accepted for certification if

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it meets all of the conditons under Subpart A except for
location in a shortage area and is approved by the Secretary

FED - J0013 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)

Type Standard

Regulation Definition

Interpretive Guideline

The facility must meet rural area requirements under either
491.5(c)(1) or 491.5(c)(2).

FED - J0014 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)(1)

Type Element

Regulation Definition

Interpretive Guideline

Rural areas are areas not delineated as urbanized areas in the
last census conducted by the Census Bureau.

FED - J0015 - RURAL AREA REQUIREMENTS

Title RURAL AREA REQUIREMENTS

CFR 491.5(c)(3)

Type Element

Regulation Definition

Interpretive Guideline

Included in the classification of rural areas are those portions
of extended cities that the Census Bureau has determined to be

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rural.

FED - J0016 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)

Type Standard

Regulation Definition

The facility meets the shortage area requirements under the Public Health Service Act section 1302(7) or section 332(a)(1)(A).

Interpretive Guideline

FED - J0017 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)(1)

Type Element

Regulation Definition

Determination of shortage of personal health services (under section 1302(7) of the Public Health Service Act).

Interpretive Guideline

FED - J0018 - SHORTAGE AREA REQUIREMENTS

Title SHORTAGE AREA REQUIREMENTS

CFR 491.5(d)(2)

Type Element

Regulation Definition

Determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Service Act).

Interpretive Guideline

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FED - J0019 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

CFR 491.6

Type Condition

Regulation Definition

Physical plant and environment.

Interpretive Guideline

A. Physical Plant Safety.--To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review. Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.

B. Preventive Maintenance.--A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)) and inspection of the facility to assure that services are rendered in a clean and orderly environment. Inspection schedules and reports should be available for review by the surveyor.

C. Non-medical Emergencies.--Review written documentation and interview clinic personnel to determine what instructions for non-medical emergency procedures have been provided and whether clinic personnel are familiar with appropriate procedures. Non-medical emergency procedures may not necessarily be the same for each clinic.

FED - J0020 - CONSTRUCTION

Title CONSTRUCTION

CFR 491.6(a)

Type Standard

Regulation Definition

The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

Interpretive Guideline

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FED - J0021 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)

Type Standard

Regulation Definition

Interpretive Guideline

The clinic has a preventive maintenance program.

FED - J0022 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic has a preventive maintenance program to ensure that all essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition.

FED - J0023 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(2)

Type Element

Regulation Definition

Interpretive Guideline

The clinic has a preventive maintenance program to ensure that drugs and biologicals are appropriately stored.

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FED - J0024 - MAINTENANCE

Title MAINTENANCE

CFR 491.6(b)(3)

Type Element

Regulation Definition

Interpretive Guideline

The clinic has a preventive maintenance program to ensure that the premises are clean and orderly.

FED - J0025 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)

Type Standard

Regulation Definition

Interpretive Guideline

The clinic assures the safety of patients in case of nonmedical emergencies.

FED - J0026 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic assures the safety of patients in case of nonmedical emergencies by training staff in handling emergencies.

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FED - J0027 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(2)

Type Element

Regulation Definition

The clinic assures the safety of patients in case of nonmedical emergencies by placing exit signs in appropriate locations.

Interpretive Guideline

FED - J0028 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

CFR 491.6(c)(3)

Type Element

Regulation Definition

The clinic assures the safety of patients in case of nonmedical emergencies by taking appropriate measures that are consistent with the conditions of the area in which the clinic is located.

Interpretive Guideline

FED - J0029 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

CFR 491.7

Type Condition

Regulation Definition

Organizational structure.

Interpretive Guideline

A. Basic Requirements.--Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of §491.8, and has adequate written material covering organization policies, including lines of

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authority and responsibilities.

B. Written Policies.--Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic's operation.

C. Disclosure of Names and Addresses.--The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction.

Any entity may organize itself as an owner of a RHC. The types of organizations being referred to are described in answers to question IV on the Request to Establish Eligibility. These range from:

- o A physician in a private general practice located in a shortage area who employs either a nurse practitioner, certified nurse-midwife or a physician assistant;
- o A nurse practitioner, certified nurse-midwife or a physician assistant in solo practice in a shortage area who develops the required relationship with a physician for medical direction; to
- o Organizations either for profit or not for profit who own primary care clinics located in shortage areas.

Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the State.

FED - J0030 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)

Type Standard

Regulation Definition

The basic requirements of organizational structure are provided.

Interpretive Guideline

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FED - J0031 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic is under the medical direction of a physician and has a health care staff that meets the requirements of 491.8.

FED - J0032 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.7(a)(2)

Type Element

Regulation Definition

Interpretive Guideline

The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

FED - J0033 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)

Type Standard

Regulation Definition

Interpretive Guideline

The clinic discloses the names and addresses of owners and responsible personnel.

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FED - J0034 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic discloses the names and addresses of its owners.

FED - J0035 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(2)

Type Element

Regulation Definition

Interpretive Guideline

The clinic discloses the name and address of the person principally responsible for directing the operation of the clinic.

FED - J0036 - DISCLOSURE OF PERSONNEL

Title DISCLOSURE OF PERSONNEL

CFR 491.7(b)(3)

Type Element

Regulation Definition

Interpretive Guideline

The clinic discloses the name and address of the person responsible for medical direction.

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FED - J0037 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

CFR 491.8

Type Condition

Regulation Definition

Staffing and staff responsibilities are identified and provided.

Interpretive Guideline

A. Sufficient Staffing.--The staffing described in 42 CFR 491.8(a) is the minimum staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When item J42 on the SRF is marked no, explain, with reasonable detail, the circumstances (and efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician, physician assistant, certified nurse-midwife or nurse practitioner member of the staff reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide some type of documentation showing the its good faith effort to obtain staff. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. The loss of a physician assistant or nurse practitioner staff member may require a temporary adjustment of the clinic's operating hours or services and an adjustment in the scheduled visits by the physician(s) providing medical direction. The loss of the physician member will require the clinic to make temporary arrangements for medical direction with another physician(s), and this might alter the scheduled times the physician is present in the clinic. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification. It is the responsibility of the clinic to promptly advise you of any changes in staffing which would affect its certification status.

B. Staffing Availability.--A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)(10)) or physician assistant must be available to furnish patient care services at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant must be available to furnish patient care services at least 50 percent of the scheduled operating hours during which RHC services are offered, even though a physician is present in the clinic on a full-time basis during the time RHC services are offered. The phrase "available to furnish patient care services" means (1) providing RHC services in the clinic; (2) being physically present in the clinic even

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though not providing RHC services; or (3) providing RHC services to clinic patients outside the clinic. These services must be RHC services. Items (1) and (2) indicate that a physician, physician assistant, certified nurse-midwife or nurse practitioner is present on the premises, not on call, during the scheduled operating hours when RHC services are offered at the facility. Item (3) refers to that part of the clinic's operating schedule utilized in providing RHC services outside the clinic.

A RHC's total operating schedule, therefore, consists of offering RHC services at the clinic, as well as providing RHC services to patients outside the clinic. Determinants of how a clinic schedules its operating time include the size of the required staff, patient population, and where the services need to be provided. Some clinics, within their scheduled hours, may be able to concurrently offer RHC services both on and off the clinic's premises, whereas other clinics may have to schedule separate hours for offering the services on and off the clinic's premises (e.g., a clinic's total operating schedule may be from 9 a.m. to 5 p.m. daily, with on-premises services offered from 9 a.m. to 3 p.m., and off-premises services offered from 3 p.m. to 5 p.m.).

Section 1861(aa)(2)(J) of the Act requires that a physician assistant, certified nurse-midwife or nurse practitioner must be available to provide patient care services during at least 50 percent of the RHC's total operating schedule. Therefore, a physician must provide needed services at other times during the clinic's scheduled operating hours. A RHC which does not have a physician, physician assistant, certified nurse-midwife or nurse practitioner on the premises to render services during the scheduled operating hours of the clinic does not meet the requirements of §1861(aa)(2) of the Act, even though the 50 percent requirement may be met.

The following are examples of how determinations regarding these requirements may be made. A clinic has a total operating schedule of from 9 to 5 Monday through Friday, and from 9 to 1 on Saturday (44 hours a week). RHC services are offered from 10 to 5 Tuesday through Friday (28 hours a week, which satisfies the 51 percent requirement). A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services from 10 to 5 Tuesday through Friday (28 hours a week). Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 14 hours (50 percent of 28 hours) to furnish patient care services.

In some cases, the clinic's weekly schedule may not be a logical period of time on which to base these determinations, and consideration of the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when a clinic has a very limited total operating schedule and the schedule offering RHC services is concentrated in a specified period of the biweekly or monthly total schedule. An example would be a clinic that is open only every other Tuesday and Friday from 10 to 4 (24 hours a month), and RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). In this situation, it is appropriate to consider the

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clinic's total monthly operating schedule for determining whether RHC services are offered during at least 51 percent of the schedule. A physician, a nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services every other Tuesday from 10 to 4, and one Friday from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 9.18 hours to furnish patient care services.

C. Staff Responsibilities.--The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

1. Physician Responsibilities.--Ascertain through written documentation, such as dates and signatures, that the physician staff member satisfactorily meets the requirement of periodically reviewing the clinic's patient records, provides medical orders, and provides medical care services to the patients.

A physician member is required to be present in the clinic for sufficient periods of time to perform the duties and responsibilities described in 42 CFR 491.8(b)(i), (ii), and (iii). The term "sufficient periods of time" requires relative evaluations. There are a number of elements to consider in weighing what would constitute a reasonable time sufficient to discharge the physician member's responsibilities. These elements include: patient case load and mix (type), number of patient care records which must be reviewed in order to establish a good overview for adherence to policies and principles of quality patient care, number of patient care records which require review and discussion of specific health problems and regimens of therapy; need for consultative time with other members of the clinic's staff; need for revision to the clinic's patient care guidelines; and need for time to provide medical care to patients. Time required to accomplish these activities will fluctuate. Thus, the "sufficient time" the physician must spend in the clinic will vary. The survey should verify the time spent in the clinic by the physician for consulting records, etc.

Extraordinary circumstances which constitute exceptions to the requirement that the physician member be present in the clinic at least once every 2 weeks for "sufficient time" to discharge the physician's responsibilities are primarily nonrecurring circumstances beyond the control of the physician and which postpone (not cancel) the visit. These circumstances include illness, extreme weather or driving conditions of short duration, or those emergencies which occur in the physician's practice and require his presence elsewhere. When nonrecurring circumstances cause postponement of the physician's visit, they should be documented in the clinic's records.

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In some instances, recurring extraordinary circumstances may constitute reasonable exception to the physician's presence requirement. This type of exception requires specific approval from the CMS RO for certification purposes, and must be documented by the surveyor. The essential areas for consideration of this exception would include:

- o The remoteness of the clinic (due to extraordinary distance and inaccessibility of the terrain) make frequent travel impossible or unreasonable;
- o The remoteness of the physician member's location has already placed the physician in an extraordinary extended practice and/or designated shortage area and required visits at least once in every 2 week period to a clinic located at a great distance would severely detract from the physician's practice; or
- o It is clearly established in advance that continuing conditions are known to be expected (snow, flood, bridge repair, etc.) which will make reasonable access to the clinic not possible for extended periods of time.

2. Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities.--The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is periodically performing the necessary responsibilities listed under J51, CMS- 30.

FED - J0038 - STAFFING

Title STAFFING

CFR 491.8(a)

Type Standard

Regulation Definition

Adequate staffing is provided.

Interpretive Guideline

FED - J0039 - STAFFING

Title STAFFING

CFR 491.8(a)(1)

Type Element

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Regulation Definition

Interpretive Guideline

The clinic has a health care staff that includes one or more physicians and one or more physician's assistants or nurse practitioners.

FED - J0040 - STAFFING

Title STAFFING

CFR 491.8(a)(2)

Type Element

Regulation Definition

Interpretive Guideline

The staff (nurse practitioner, physician, or physician's assistant) meets qualification requirements of section 491.2(b),(c),(d).

FED - J0041 - STAFFING

Title STAFFING

CFR 491.8(a)(6)

Type Element

Regulation Definition

Interpretive Guideline

A physician, nurse practitioner, physician's assistant, nurse midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times during the clinic's regular hours of operation. A nurse practitioner or a physician's assistant is available to furnish patient care services during at least 60% of the clinic's regular hours of operation.

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FED - J0042 - STAFFING

Title STAFFING

CFR 491.8(a)(5)

Type Element

Regulation Definition

The staff is sufficient to provide the services essential to the operation of the clinic.

Interpretive Guideline

FED - J0045 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)

Type Standard

Regulation Definition

Physician responsibilities are identified and accomplished.

Interpretive Guideline

FED - J0046 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(1)(i)

Type Element

Regulation Definition

The physician provides medical direction for the clinic's health care activities and consultation for, and medical supervision of, the health care staff.

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FED - J0047 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(1)(ii)

Type Element

Regulation Definition

The physician, in conjunction with the nurse practitioner and/or the physician assistant participates in developing, executing, and periodically reviewing the clinic's written policies and the services provided to Federal program patients.

Interpretive Guideline

FED - J0048 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(1)(iii)

Type Element

Regulation Definition

The physician periodically reviews the clinic's patient records, provides medical orders, and provides medical care services to the patients of the clinic.

Interpretive Guideline

FED - J0049 - PHYSICIAN RESPONSIBILITIES

Title PHYSICIAN RESPONSIBILITIES

CFR 491.8(b)(2)

Type Element

Regulation Definition

A physician is present for sufficient periods of time, at least

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once in every two week period, to provide medical direction, medical care services, consultation, and supervision, and is available through direct telephone contact for consultation, assistance with medical emergencies, or patient referral. Extraordinary circumstances are documented in the records of the clinic.

FED - J0050 - PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

Title PHYSICIAN ASST/NURSE PRACT.
RESPONSIBILITIES
CFR 491.8(c)

Type Standard

Regulation Definition

Physician's assistant and nurse practitioner responsibilities are identified and accomplished.

Interpretive Guideline

FED - J0051 - PHYSICIAN ASST/NURSE PRACT. RESPONSIBILITIES

Title PHYSICIAN ASST/NURSE PRACT.
RESPONSIBILITIES
CFR 491.8(c)(1)

Type Element

Regulation Definition

The physician's assistant and the nurse practitioner members of the clinic's staff must participate in the development, execution, and periodic review of the written policies governing the services the clinic furnishes; provide services in accordance with those policies; arranges for services that cannot be provided at the clinic; assure that adequate patient health records are maintained and transferred as required; participate with a physician in a periodic review of the patient's health records.

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FED - J0052 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

CFR 491.9

Type Condition

Regulation Definition

The clinic provides services which are consistent with its certification.

Interpretive Guideline

A. Basic Requirements

1. State and Local Laws.--Know the State's position, generally, with respect to implementing the Federal RHC requirements vis-a-vis the State's Medical Practice Act, Nurse Practice Act, the Pharmacy Act, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91- 513) and the general scope of practice permitted for nurse practitioners, certified nurse-midwives and physician assistants.

Some States may have legal impediments because applicable practice acts prohibit nurse practitioners, certified nurse-midwives and/or physician assistants from independent acts of medical diagnosis and treatment precluding the fullest implementation of the Federal RHC requirements.

This does not necessarily preclude participation by a RHC that provides RHC services (physician-type services) furnished by nurse practitioners, certified nurse-midwives and/or physician assistants under the direct supervision (as distinguished from indirect supervision) of a physician. Therefore, inquiries to State authorities about compliance with the Federal RHC requirements, as well as decisions concerning applicant RHCs, must be weighed against several determinations, including:

- o The medical direction and supervision described in the regulations is the minimum requirement; many participating RHCs operate with greater medical direction and supervision than these minimums.
- o The word "supervision" does not automatically equate with direct, over the shoulder supervision. Many States requiring physician supervision of medical acts performed by a nurse practitioner or a physician assistant have held that performances of such medical acts under written patient care guidelines developed and/or approved by a licensed physician satisfy the requirement of supervision.

2. Providing Rural Health Clinic Services.--The law describes a RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services; usually, related health care services such as the "other ambulatory services" covered by Medicaid State plans. Certification as a RHC applies to the facility as a whole and the total operating schedule of the facility (the

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hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services. If onsite observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician's office), then the clinic may satisfy the "primarily engaged" requirement providing that RHC services are offered at least 51 percent of the total operating schedule. The time RHC services are offered may differ from the total operating schedule of the facility, but may not be less than 51 percent of this total operating schedule.

If there is a question about this condition, review a sample of patient health records covering a reasonable period of time to determine the majority of specific services actually furnished.

An example of a clinic schedule that combines RHC services and "other ambulatory services" would be a clinic in which primary medical care is offered from 9 to 4 Monday through Thursday, and dental services are offered from 9 to 4 on Friday.

B. Patient Care Policies Requirements.--Review the clinic's policies and ascertain who developed them. Where changes in clinic personnel and/or clinic administration make it impossible or not relevant to ascertain who developed the policies, it is necessary to ascertain that the current physician member(s) and the nurse practitioner, certified nurse-midwife, and/or physician assistant member(s) of the staff have an indepth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed- to written changes in them. If a clinic's organizational structure includes a governing body, ascertain whether the governing body has ultimate authority in approving the patient care policies and, if so, when such approval was last given. While clinics frequently seek the participation of other health care professionals in developing patient care policies (particularly the written guidelines for the medical management of health problems) the term "a group of professional personnel" is not restricted to health care professionals. In some cases, the clinic will have involved health care professionals representatives to a hospital with which the clinic has an agreement for patient referral. In any event, one member of the group of three or more may not be a member of the clinic's staff, and professions which are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.

The requirements concerning written policies address four areas:

1. Description of Services.--A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. The services furnished by the clinic should be described in a manner than informs potential patients of the types of health care available at the clinic, as well as setting the parameters of the scope of what services are furnished through referral. Such statements as the following sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab

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tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning, complete dental care, emergency medical care. Statements such as "complete management of common acute and chronic health problems" standing alone, do not sufficiently describe services.

Additional services, furnished through referral, are sufficiently described in such statements as: Arrangements have been made with X hospital for clinic patients to receive the following services if required: specialized diagnostic and laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.

2. Guidelines for Medical Management.--The clinic's written guidelines for the medical management of health problems include a description of the scope of medical acts which may be undertaken by the physician assistant, certified nurse-midwife, and/or nurse practitioner. They represent an agreement between the physician providing the clinic's medical direction and the clinic's physician assistant, certified nurse-midwife, and/or nurse practitioner on the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken without direct, over the shoulder physician supervision. They describe the regimens to be followed and stipulate the conditions in the illness or health care management at which consultation or referral is required.

Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies.

The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition, its etiology, its clinical features, recommended laboratory studies, differential diagnosis, treatment procedures, complications, consultation/referral required, and follow-up.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements. They:

- o Are comprehensive enough to cover most health problems that patients usually see a physician about;
- o Describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant;
- o Describe the medical conditions, signs, or developments that require consultation or referral; and

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- o Are compatible with applicable State laws.

A number of patient care guidelines have been published by members of the medical profession. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the essential elements described above.

3. Drugs and Biologicals.--Written policies cover at least the following elements:

- o Requirements dealing with the storage of drugs and biologicals in original manufacturer's containers to assure that they maintain their proper labeling and packaging;
- o Requirements dealing with outdated, deteriorated, or adulterated drugs and biologicals being stored separately so that they are not mistakenly used in patient care prior to their disposal in compliance with applicable laws;
- o Requirements dealing with storage in a space that provides proper humidity, temperature, and light to maintain the quality of drugs and biologicals;
- o Requirements for a securely constructed locked compartment for storing drugs classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970;
- o Requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV, and V; with Schedule II drugs being accounted for separately;
- o Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;
- o Requirements dealing with the complete and legible labeling of containers used to dispense drugs and biologicals to patients;
- o Requirements concerning the availability of current drug references and antidote information; and
- o Requirements dealing with prescribing and dispensing drugs in compliance with applicable State laws.

4. Review of Policies.--The group of professional personnel, which can be the governing body acting as the group, is responsible for an annual review of patient care policies.

C. Direct Services.--The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services which must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.

The clinic's laboratory is to be treated as a physician's office for the purpose of licensure and meeting health and safety standards. The listed laboratory services are considered essential for the immediate diagnosis and treatment of

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the patient. To the extent they can be provided under State and local law, the nine services listed in J61, CMS-30, are considered the minimum the clinic should make available through use of its own resources.

If any of these laboratory services cannot be provided at the clinic under State or local law, that laboratory service is not required for certification. Some clinics are not able to furnish the nine services, even though they may be allowed to do so under State and local law, without involving an arrangement with a Medicare approved laboratory.

Those clinics unable to furnish all nine services directly when allowed to by State and local law should be given deficiencies. Such deficiencies should not be considered sufficiently significant to warrant termination if the clinic has an agreement or arrangement with an approved laboratory to furnish the basic laboratory service it does not furnish directly, especially if the clinic is making an effort to meet this requirement.

FED - J0053 - BASIC REQUIREMENTS

Title BASIC REQUIREMENTS

CFR 491.9(a)

Type Standard

Regulation Definition

The clinic is primarily engaged in providing outpatient health services and meets all other conditions of Subpart A.

Interpretive Guideline

FED - J0054 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)

Type Standard

Regulation Definition

Patient care policies are complete.

Interpretive Guideline

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FED - J0055 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(1)

Type Element

Regulation Definition

The clinic's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

Interpretive Guideline

FED - J0056 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(2)

Type Element

Regulation Definition

Patient care policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician's assistants or nurse practitioners. At least one member of the group is not a member of the clinic staff.

Interpretive Guideline

FED - J0057 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(3)

Type Element

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Regulation Definition

The patient care policies include a description of the services the clinic furnishes directly and those furnished through agreement or arrangement; guidelines for the medical management of health problems which include the conditions requiring medical consultation and or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic; and rules for the storage, handling, and administration of biologicals.

Interpretive Guideline

FED - J0058 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

CFR 491.9(b)(4)

Type Element

Regulation Definition

The patient care policies are reviewed at least annually by the group of professional personnel which includes one or more physicians and one or more physician's assistants or nurse practitioners, and are reviewed as necessary by the clinic.

Interpretive Guideline

FED - J0059 - DIRECT SERVICES

Title DIRECT SERVICES

CFR 491.9(c)

Type Standard

Regulation Definition

Adequate direct services are provided.

Interpretive Guideline

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FED - J0060 - DIRECT SERVICES - GENERAL

Title DIRECT SERVICES - GENERAL

CFR 491.9(c)(1)

Type Element

Regulation Definition

The clinic staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guideline

FED - J0061 - DIRECT SERVICES - LABORATORIES

Title DIRECT SERVICES - LABORATORIES

CFR 491.9(c)(2)

Type Element

Regulation Definition

The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including chemical examinations of urine by stick or tablet methods or both (including urine ketones), microscopic examination of urine sediment, hemoglobin or hematocrit, blood glucose, examination of stool specimens for occult blood, pregnancy tests, and primary culturing for transmittal to a certified laboratory.

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FED - J0062 - DIRECT SERVICES - EMERGENCY

Title DIRECT SERVICES - EMERGENCY

CFR 491.9(c)(3)

Type Element

Regulation Definition

The clinic provides medical emergency procedures as a first response to common life-threatening injuries and acute illness, and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

Interpretive Guideline

FED - J0063 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)

Type Standard

Regulation Definition

Agreements or arrangements must be accomplished for all services provided outside of the clinic.

Interpretive Guideline

FED - J0064 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)(1)

Type Element

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Regulation Definition

The clinic has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including (i) inpatient hospital care, (ii) physician(s) services, and (iii) additional and specialized diagnostic and laboratory services that are not available at the clinic.

Interpretive Guideline

FED - J0065 - SERVICES PROVIDED BY AGREEMENTS

Title SERVICES PROVIDED BY AGREEMENTS

CFR 491.9(d)(2)

Type Element

Regulation Definition

If patient service agreements are not in writing, there is evidence that patients referred by the clinic are being accepted and treated.

Interpretive Guideline

FED - J0066 - PATIENT HEALTH RECORDS

Title PATIENT HEALTH RECORDS

CFR 491.10

Type Condition

Regulation Definition

Patient health records are adequately maintained.

Interpretive Guideline

A. Records System.--The clinic is to maintain patient health records in accordance with its written policies and procedures. These records are the responsibility of a designated member of the clinic's professional staff and should be maintained for each person receiving health care services. All records should be kept at the clinic site so that they are available when patients may need unscheduled medical care.

Examine a randomly selected sample of health records to determine if appropriate information, as related in J70 of the SRF and 42 CFR 491.10(a)(3), is included. This listing is the minimum requirement for record maintenance. If

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deficiencies are found while reviewing the records, review additional records to determine the prevalence of these deficiencies.

Record on the SRF the number of records reviewed and deficiencies found, if any, and as questions arise concerning the records, discuss them with the person responsible for record maintenance.

B. Protection of Record Information.--The clinic must ensure the confidentiality of the patient's health records and provide safeguards against loss, destruction, or unauthorized use of record information. Ascertain that information regarding the use and removal of records from the clinic and the conditions for release of record information is in the clinic's written policies and procedures. The patient's written consent is necessary before any information not authorized by law may be released.

C. Retention of Records.--Review the clinic policy pertaining to the retention of patient health records. This policy reflects the necessity of retaining records at least 6 years from the last entry date or longer if required by State statute.

FED - J0067 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)

Type Standard

Regulation Definition

Interpretive Guideline

An appropriate records system is being used by the clinic.

FED - J0068 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic maintains a clinical record system in accordance with written policies and procedures.

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FED - J0069 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(2)

Type Element

Regulation Definition

A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guideline

FED - J0070 - RECORDS SYSTEM

Title RECORDS SYSTEM

CFR 491.10(a)(3)

Type Element

Regulation Definition

For each patient receiving health care services, the clinic maintains a record that includes, as applicable, identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; reports of physical examinations, diagnostic and laboratory test results, and consultative findings; all physician's orders, reports of treatments and medications and other pertinent information necessary to monitor the patient's progress; and signatures of the physician or other health care professional.

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FED - J0071 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)

Type Standard

Regulation Definition

Interpretive Guideline

The clinic provides adequate protection of record information.

FED - J0072 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(1)

Type Element

Regulation Definition

Interpretive Guideline

The clinic maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

FED - J0073 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(2)

Type Element

Regulation Definition

Interpretive Guideline

Written policies and procedures govern the use and removal of records from the clinic and the conditions for release of information.

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FED - J0074 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

CFR 491.10(b)(3)

Type Element

Regulation Definition

The patient's written consent is required for release of information not authorized to be released without such consent.

Interpretive Guideline

FED - J0075 - RETENTION OF RECORDS

Title RETENTION OF RECORDS

CFR 491.10(c)

Type Standard

Regulation Definition

The patient's records are retained for at least 6 years from the date of last entry, and longer if required by State statute.

Interpretive Guideline

FED - J0076 - PROGRAM EVALUATION

Title PROGRAM EVALUATION

CFR 491.11

Type Condition

Regulation Definition

An adequate program evaluation has been completed.

Interpretive Guideline

An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other

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appropriate professionals. The surveyor clarifies for the clinic that the State survey does not constitute any part of this program evaluation.

The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same personnel. However, if the evaluation is not done all at once, no more than a year should elapse between evaluating the same parts. For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of each fiscal year; and its utilization of clinic services, clinic records, and health care policies evaluated 6 months later by a group of health care professionals.

If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.

A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered in the evaluation. What will be covered should be consistent with the requirements of 42 CFR 491.11. Record this information under the explanatory statements on the SRF.

Review dated reports of recent program evaluations to verify that such items are included in these evaluations. When corrective action has been recommended to the clinic, verify that such action has been taken or that there is sufficient evidence indicating the clinic has initiated corrective action.

FED - J0077 - ANNUAL TOTAL PROGRAM EVALUATION

Title ANNUAL TOTAL PROGRAM EVALUATION

CFR 491.11(a)

Type Standard

Regulation Definition

The clinic carries out, or arranges for an annual evaluation of its total program.

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FED - J0078 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)

Type Standard

Regulation Definition

The annual clinic evaluation includes a review of all services, clinical records, and policies.

Interpretive Guideline

FED - J0079 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(1)

Type Element

Regulation Definition

The evaluation includes review of the utilization of clinic services, including at least the number of patients served and the volume of services is reviewed annually.

Interpretive Guideline

FED - J0080 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(2)

Type Element

Regulation Definition

The evaluation includes review of a representative sample of both active and closed clinical records.

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FED - J0081 - EVALUATION REVIEW CRITERIA

Title EVALUATION REVIEW CRITERIA

CFR 491.11(b)(3)

Type Element

Regulation Definition

Interpretive Guideline

The evaluation includes review of the clinic's health care policies.

FED - J0082 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)

Type Standard

Regulation Definition

Interpretive Guideline

The purpose of the annual evaluation is to determine if services were appropriate and policies were followed.

FED - J0083 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(1)

Type Element

Regulation Definition

Interpretive Guideline

The purpose of the annual examination is to determine whether the utilization of services was appropriate.

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FED - J0084 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(2)

Type Element

Regulation Definition

Interpretive Guideline

The purpose of the annual examination is to determine whether the established policies were followed.

FED - J0085 - PURPOSE OF EVALUATION

Title PURPOSE OF EVALUATION

CFR 491.11(c)(3)

Type Element

Regulation Definition

Interpretive Guideline

The purpose of the annual examination is to determine whether any changes were needed.

FED - J0086 - EVALUATION FINDINGS & ACTION TAKEN

Title EVALUATION FINDINGS & ACTION TAKEN

CFR 491.11(d)

Type Standard

Regulation Definition

Interpretive Guideline

The clinic staff considers the findings of the annual evaluation and takes corrective action if necessary.

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FED - J9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

CFR

Type Memo Tag

Regulation Definition

Interpretive Guideline